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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/016,737	01/30/1998	GERALD P. MURPHY	8511-007	7366

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NEW YORK, NY 100362711

EXAMINER

DAVIS, MINH TAM B

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 07/05/2002

Handwritten signature/initials

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/016,737

Applicant(s)

MURPHY ET AL.

Examiner

MINH-TAM DAVIS

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 April 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 1-22, 25 and 27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23, 24, 26 and 28-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Effective February 7, 1998, the Group Art Unit location has been changed, and the examiner of the application has been changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Minh-Tam Davis, Group Art Unit 1642.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Accordingly, claims 23, 24, 26, and 28-37 are being examined.

This application contains claims 1-22, drawn to an invention nonelected with traverse in Paper No.8. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

The following are the remaining rejections.

REJECTION UNDER 35 USC 112, SECOND PARAGRAPH

Rejection under 35 USC 112, second of claims 23, 24, 26, and 28-37 pertaining to having the language "directly isolated" and being confusing remains for reasons already of record in paper No.19.

Applicant amends claims 23 and 31 to recite a composition comprising a cell population having an increased number of, or at least 20 fold more, dendritic cells competent to and able to activate prostate specific antigen, as compared to "a cell population" directly isolated from peripheral blood.

Applicant asserts that the enriched dendritic cell population exposed to prostate antigen comprises an increased number of human dendritic cells competent and able to activate T cells specific to prostate antigen as compared to similar dendritic cell population directly isolated from peripheral blood that has not been exposed to prostate antigen and allowed to mature (directly isolated). Applicant further asserts that as the increased number of dendritic cells competent and able to activate cytotoxic T cells specific to a prostate antigen is a relative number depending on the overall population size, the actual amount of blood used to derive the cells is not relevant to the clarity of the claims.

Applicant's arguments set forth in paper No.22 have been considered but are not deemed to be persuasive for the following reasons:

The claims as amended is indefinite because it is not clear which cell population is directly isolated from peripheral blood, i.e. is it a population of B cells? Further, the property of "directly isolated from peripheral blood" cannot be used to distinguish the two populations, because the claimed population of dendritic cells seem to be taken directly from peripheral blood for centrifugation.

Further, since the claims do not recite that the volume of blood is the same for both samples of the claimed dendritic cells and the claimed cell population directly isolated from peripheral blood, it is not clear how one could compare the cell number in the two samples. The claimed increased number is meaningless if the blood volume of the claimed population of dendritic cells is unknown, or larger as compared to that of the cell population directly isolated from peripheral blood.

REJECTION UNDER 35 USC 102

Rejection under 35 USC 102 of claims 23, 24, and 31-36 pertaining to anticipation by Cohen et al, as evidenced by Sallusto et al, Koch et al, and Czerniecki et al, remains for reasons already of record in paper No.19.

Applicant recites the references by Zhou et al and Koski et al. Applicant asserts that Zhou et al teach that the characteristics of mature dendritic cells include expression of CD83+ phenotype. Applicant further asserts that Koski et al is an additional report from the Cohen laboratory, wherein Koski et al teach that treatment of human peripheral blood monocytes or dendritic cells with calcium ionophore led to the rapid (18 hr) acquisition of many characteristics of mature DC, including CD83 expression (summary). Moreover, Applicant asserts that mature dendritic cells, as demonstrated by Zhou et al and Sallusto, are incapable of processing antigen, and that Example 2 of Cohen is merely prophetic and cannot enable a dendritic cell population as set forth in the pending claims.

The recitation of the references by Zhou et al and Koski et al is acknowledged.

Applicant's arguments set forth in paper No.22 have been considered but are not deemed to be persuasive for the following reasons:

Koski et al teach that monocyte CD83 expression appear within 4 hrs and peaked at 20 hours of calcium ionophore treatment, whereas with a combination of cytokine treatment CD83 expression is seldom observed before 5 to 7 days of culture (p.10, first column, first paragraph). Thus one would have expected that monocytes

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treated with calcium ionophore would have immature dendritic cells that are able to activate T cells specific to a prostate antigen, provided the treatment with calcium ionophore is not prolonged, and the treated monocytes are used within 20 hours and preferably within 4 hrs after the initial treatment with calcium ionophore. Although Cohen et al do not specify the length of the calcium ionophore treatment, nor when the treated monocytes were used after calcium ionophore in Example 2, the fact that the treated monocytes taught by Cohen could reduce prostate tumor size (column 12, Example 2) indicates that the treated monocytes taught by Cohen et al have not transformed into mature dendritic cells and are able to activate T cells specific to a prostate antigen, resulting in killing prostate tumor cells.

REJECTION UNDER 35 USC 103

1. Rejection under 35 USC 103 of claim 26 pertaining to being obvious by Cohen et al, in view of Lutz et al, remains for reasons already of record in paper No.19.

Applicant argues that Cohen et al do not disclose the claimed invention, and therefore Lutz et al add nothing to render obvious the immortalized dendritic cells.

Applicant's arguments set forth in paper No.22 have been considered but are not deemed to be persuasive for the following reasons:

The claimed dendritic cells are not patentably distinct from the dendritic cells taught by Cohen et al for the reasons set forth previously and above.

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2. Rejection under 35 USC 103 of claims 28, 29 pertaining to being obvious by Cohen et al, in view of Taylor et al, remains for reasons already of record in paper No.19.

Applicant argues that Cohen et al do not disclose the claimed invention, and therefore Taylor et al add nothing to render obvious the immortalized dendritic cells. Applicant further argues that there is no suggestion in the references for the combination as suggested by the Examiner.

Applicant's arguments set forth in paper No.22 have been considered but are not deemed to be persuasive for the following reasons:

The claimed dendritic cells are not patentably distinct from the dendritic cells taught by Cohen et al for the reasons set forth previously and above.

Further, the motivation to combine the references is obvious, i.e. to preserve the previously isolated dendritic cells, as taught by Taylor et al.

3. Rejection under 35 USC 103 of claim 30 pertaining to being obvious by Cohen et al, in view of Taylor et al, further in view of Lutz et al, remains for reasons already of record in paper No.19.

Applicant argues that Cohen et al do not disclose the claimed invention, and therefore Taylor et al and Lutz et al add nothing to render obvious the immortalized dendritic cells. Applicant further argues that there is no suggestion in the references for the combination as suggested by the Examiner.

Applicant's arguments set forth in paper No.22 have been considered but are not deemed to be persuasive for the following reasons:

The claimed dendritic cells are not patentably distinct from the dendritic cells taught by Cohen et al, for the reasons set forth previously and above.

Further, the motivation to combine the references is obvious, i.e. to use the immortalized dendritic cells and to be able to maintain the cells for long term *in vitro*, by immortalizing and preserving the previously isolated dendritic cells, as taught by Taylor et al and Lutz et al.

4. Rejection under 35 USC 103 of claim 37 pertaining to being obvious by Cohen et al, in view of Stites et al, remains for reasons already of record in paper No.19.

Applicant argues that Cohen et al do not disclose the claimed invention, and therefore Stites et al add nothing to render obvious the immortalized dendritic cells. Applicant further argues that there is no suggestion in the references for the combination as suggested by the Examiner.

Applicant's arguments set forth in paper No.22 have been considered but are not deemed to be persuasive for the following reasons:

The claimed dendritic cells are not patentably distinct from the dendritic cells taught by Cohen et al, for the reasons set forth previously and above.

Further, since Stites et al teach that T cells only recognize immunogens in conjunction with MHC, which is the same as HLA molecules, and that matching HLA antigen is important in organ transplantation, the motivation to combine the references is obvious, i.e. to prevent the possibility that 1) the dendritic cells are not capable to activate T cells specific for a prostate tumor antigen, due to difference in HLA type, and 2) the possibility that the dendritic cells are rejected due to difference in HLA type.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 703-305-2008. The examiner can normally be reached on 9:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANTHONY CAPUTA can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

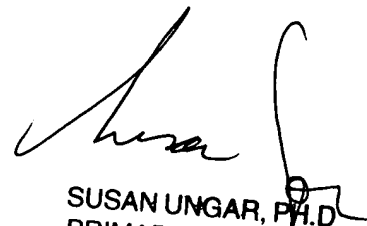
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0916.

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MINH TAM DAVIS

July 3, 2002



SUSAN UNGAR, PH.D.
PRIMARY EXAMINER